Adrenaline auto-injectors: updated advice after European review

From: Medicines and Healthcare products Regulatory Agency
Published: 15 August 2017

It is recommended that 2 adrenaline auto-injectors are prescribed, which patients should carry at all times.

Contents

1. Results of European review
2. Patient and carer instructions
3. Anaphylaxis

Advice for healthcare professionals:

- it is recommended that 2 adrenaline auto-injectors are prescribed, which patients should carry at all times
- ensure that people with allergies and their carers have been trained to use the particular auto-injector that they have been prescribed—technique varies between injectors
- encourage people with allergies and their carers to obtain and practise using a trainer device (available for free from the manufacturers’ websites)

Advice to give to people with allergies and their carers:

- it is recommended that you carry 2 adrenaline auto-injectors at all times; this is particularly important for people who also have allergic asthma because they are at increased risk of a severe anaphylactic reaction
- use the adrenaline auto-injector at the first signs of a severe allergic reaction
- take the following actions immediately after every use of an adrenaline auto-injector:
  1. call 999, ask for an ambulance and state “anaphylaxis”, even if symptoms are improving
  2. lie flat with legs raised to maintain blood flow. However, if you have breathing difficulties, you may need to sit up to make breathing easier
  3. seek help immediately after using the auto-injector and if at all possible make sure someone stays with you while waiting for the ambulance
  4. if you do not start to feel better, use the second auto-injector 5–15 minutes after the first one
- check the expiry date of the adrenaline auto-injectors and obtain replacements before they expire; expired injectors will be less effective
Results of European review

The European Medicines Agency (EMA) has completed a review of all adrenaline auto-injectors approved in the EU. The review concluded that:

- due to uncertainties about the site of drug delivery and the speed of adrenaline action within the body, it is recommended that healthcare professionals prescribe 2 auto-injectors, which patients should carry at all times
- the needle length of the device is now stated in the product information because this may be an important factor for the prescriber to consider when choosing a suitable auto-injector
- the training of patients and their carers in the correct use of the product is important and manufacturers were required to update their educational materials – see table below
- manufacturers should carry out studies in humans to more fully understand when and how much adrenaline reaches the blood stream, and how quickly and effectively it acts on body tissues when given through an auto-injector

These studies have started and will help to inform future recommendations for adrenaline auto-injectors.

Patient and carer instructions

If you prescribe adrenaline auto-injectors, you should ensure that the patient or carer thoroughly understands the indications and use of the device.

You should review with the patient and their carers the instructions and operation of the adrenaline auto-injector.

We have produced an updated advice sheet to give to patients and carers.

The table below provides links to the patient information leaflets and educational material for all adrenaline auto-injectors licenced in the UK. People with allergies and their carers can also use manufacturer websites to order trainer devices and to sign up for expiry alert services.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Patient information leaflet</th>
<th>Educational material produced by the manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emerade 150 µg, 300 µg, and 500 µg solution for injection in pre-filled pen</td>
<td><a href="#">Emerade adrenaline auto-injectors</a></td>
<td><a href="#">Emerade patient brochure</a> and <a href="#">instruction video</a></td>
</tr>
<tr>
<td>EpiPen 0.3 mg and EpiPen Jr. 0.15 mg adrenaline (epinephrine) auto-injector</td>
<td><a href="#">EpiPen</a> and <a href="#">EpiPen Jr auto-injectors</a></td>
<td><a href="#">EpiPen user guide</a> and <a href="#">instruction video</a></td>
</tr>
<tr>
<td>Jext 150 µg and Jext 300 µg solution for injection in pre-filled pen</td>
<td><a href="#">Jext pre-filled pens</a></td>
<td><a href="#">Jext instructions for use and instruction video</a></td>
</tr>
</tbody>
</table>
Anaphylaxis

The Resuscitation Council recommends an intramuscular injection of adrenaline in the outer thigh to be treatment of choice for someone having an anaphylactic reaction. Because the onset of anaphylaxis can be very fast, the individual should use an adrenaline auto-injector at the first signs of a severe reaction, then call for emergency medical help. Signs of a severe reaction include:

- swelling in the throat (altered voice, difficulty swallowing or breathing)
- wheezing
- dizziness, feeling faint, tiredness (symptoms of low blood pressure)

If in doubt about severity, or if previous reactions have been severe, the individual should use an adrenaline auto-injector. If the individual does not feel better after the first injection, the second auto-injector should be used 5–15 minutes after the first.

Article citation: Drug Safety Update volume 11 issue 1, August 2017: 3.


Document information

Published: 15 August 2017

From: Medicines and Healthcare products Regulatory Agency

Therapeutic area: Paediatrics and neonatologyRespiratory disease and allergy